REMARKS

The Office Action mailed June 18, 2003, set a three-month shortened statutory period for response expiring September 18, 2003. The period for response is extended to December 18, 2003, pursuant to the petition for extension of time under 37 CFR 1.136(a) submitted herewith. This amendment is therefore timely filed.

Before this amendment, Claims 1-32 and 35-38 were in the application, Claims 33 and 34 having been cancelled without prejudice to the prosecution thereof in a continuing application in the Amendment filed February 19, 2002.

Claims 6-32 and 35-38 stand withdrawn from consideration as drawn to non-elected subject matter.

The application is amended to add new Claim 39 drawn to the polypeptide of SEQ ID No. 6, the elected species. The application, as amended, contains Claims 1-32 and 35-39.

Claims 1-5 are rejected under 35 U.S.C. § 101 for the reasons previously given in Paper No. 15, essentially that it had not been demonstrated that SR-p70 and p73 are identical, and that the teachings of the Br. J. Cancer, 2001, reference could not be evaluated on the basis of the abstract. In the Response filed February 19, 2002, Applicants submitted both a copy of the entire Br. J. Cancer 2001 reference and a showing that SEQ ID No. 6 (SR-p70) of the instant application and SEQ ID No. 1 (p73) of WO 99/66946 are identical. However, the documents were not considered by the Examiner on the grounds that Applicants had not shown good and sufficient reasons why the documents had not been presented earlier.

In the instant Office Action, the Examiner acknowledges that SEQ ID No. 6 is identical, residue by residue, to p73 of WO 99/66946, but maintains that the Br. J. Cancer 2001 reference teaches that the role of p73 in cancer has not yet been fully determined, and cites numerous other references in support of the position that the role of p73 in carcinogenesis is ambiguous; that p73 may exist in several isoforms; that different isoforms of proteins unrelated to p73 may exhibit different functions; that cultured cells may differ in properties from *in vivo* cells; and that it cannot be determined whether p73 is expressed *in vivo*. Although the Examiner's rather lengthy discussion of p73 may be interesting, it is largely beside the point.

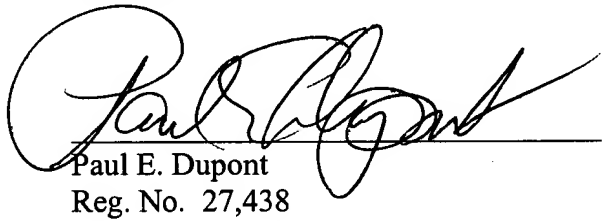
In fact, and as acknowledged by the Examiner, SR-p70 and p73 are indeed identical. Tominaga et al teach that p73 accumulates in various tumor cells, referring to "an increasing number of publications describing p73 accumulation in tumoral cells" (Summary) and noting that "several consistent reports indicate that the p73 protein accumulates in the nucleus of tumor cells from different types of cancer" (p. 57, right-hand column). Ikawa et al also teach that p73 is differentially expressed in a number of cancers as compared to normal tissue (p. 1157, right-hand column). Tominaga et al teach that sera from cancer patients containing p73 antibodies are detected by reaction with p73. Thus, that the role of p73 in cancer may not be fully elucidated, as urged by the Examiner, is irrelevant to its use in detecting p73 antibodies in the sera of cancer patients. That p73 may exist in several isoforms does not alter the fact that the p73 of Tominaga et al, whatever isoform it happens to be, detects p73 antibodies in the sera of cancer patients. Moreover, even if p73 is not differentially expressed in all possible tumor types, it does provide a means of detecting those tumors in which it is differentially expressed. Lastly, regardless of whether p73 is expressed *in vivo* or in cell culture, the fact is that the p73 of Tominaga et al was effective in detecting p73 antibodies in the sera of cancer patients. Therefore, given that p73 and SR-p70 are identical (in fact, the p73 of Tominaga et al was derived from the constructs obtained from D. Caput, one of the inventors in the instant application, Tominaga et al, Acknowledgements, page 62), Applicants do indeed teach a utility for the claimed invention. Accordingly, reconsideration and withdrawal of the rejection of Claims 1-5 under 35 U.S.C. § 101 are requested.

Claims 1-5 are rejected under 35 U.S.C. § 112, first paragraph, for lack of enablement. In support of the rejection, the Examiner provides a lengthy discussion of the degree of homology between p73 and p53 and the DNA binding regions thereof, and concludes that the respective functions of p73 and p53 would not be the same. It is further urged that there are six p73 isoforms and that it is not known whether p73 is actually expressed *in vivo*, and that it is therefore unclear how one would use p73 in treating the phenomena of carcinogenesis or in the prophylactic, diagnostic or therapeutic methods suggested by Applicants. The Examiner does however acknowledge that Tominaga et al teach the detection of p73 autoantibodies in patients with various types of cancer. Nevertheless, it is urged that Tominaga et al do not teach which splice variant of SR-p70 the autoantibodies are specific for, or whether SR-p70 is expressed *in vivo* and concludes that no evidence has been provided which would allow one of skill in the art to predict that the

invention will function as contemplated, and that the specification provides insufficient guidance on how to use the claimed invention with a reasonable expectation of success.

The instant specification describes SR-p70 (SEQ ID No. 6), which is identical to p73; teaches the manner of making it (specification page 11, line 6, to page 13, line 22) and teaches how to use it (specification p. 15, lines 14-26), which use is confirmed by Tominaga et al. Accordingly, the instant specification fully meets the requirements of 35 U.S.C. § 112. The issues raised by the Examiner regarding the degree of homology between p73 and p53, the different p73 isoforms, and whether p73 is expressed *in vivo* simply do not negate Applicants' teaching of the manner of making SR-p70 (identical to p73) and the manner of using it to identify p73 autoantibodies in the sera of cancer patients regardless of its degree of homology with p53, or its particular isoform, or whether it is expressed *in vivo*. Reconsideration and withdrawal of the rejection under 35 U.S.C. § 112 is requested.

Respectfully submitted,



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